K110546
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510(k) Summary
for
Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey

JUL 27 2011

1. SPONSOR

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2. CONSULTANT/CONTACT

Medical Device Consultants, Inc.
11440 West Bernardo Drive, Suite 300
San Diego, CA 92127
Telephone: 858-753-1961
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Primary Contact: Ron Warren
Date Prepared: February 24, 2011

3. DEVICE NAME

Proprietary Name:	Derma Sciences Medihoney Hydrogel Sheet Dressings (Adhesive and Non-adhesive) with Leptospermum Honey
Common/Usual Name:	Wound Dressing
Classification Name:	Dressing

4. PREDICATE DEVICES

- Medihoney Primary Wound Dressings with Active Manuka Honey (K072956)
- L-Mesitran® Dressing Family (K053613)

5. DEVICE DESCRIPTION

Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey are sterile, single-use wound care dressings for use in moist wound management. The dressings are comprised of 63% Leptospermum Honey and hydrogel both with and without an adhesive border. The Derma Sciences Medihoney Hydrogel Sheet

Dressings with Leptospermum Honey are offered in the following sizes: 2 ¾" x 2 ¾", 4 1/3" x 4 1/3", 6" x 9", 4 1/3" x 4 1/3" (adhesive border), 6" x 6" (adhesive border).

6. INDICATION FOR USE/INTENDED USE

The Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey provide a moist environment conducive to wound healing and are indicated for non-draining to lightly exuding wounds.

For over the counter use, Medihoney Hydrogel Sheet Dressings with Leptospermum Honey may be used for:

- minor abrasions
- minor cuts
- minor scalds
- minor burns

Under the supervision of a healthcare professional, The Derma Sciences Medihoney Hydrogel Sheet Dressings provide a moist environment conducive to wound healing and are indicated for non-draining to lightly exuding wounds. The Medihoney Hydrogel Sheet Wound Dressings are intended for the management of the following:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The technological characteristics of the Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey, the parent Medihoney Primary Wound Dressings with Manuka Honey, and the L-Mesitran® Dressing Family are substantially equivalent in that they are all honey based dressings suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions. In addition, both the proposed and the L-Mesitran® Dressing Family predicate devices are intended for both OTC and prescription use.

The modifications made to the Medihoney Wound Dressings with Manuka Honey Dressings to produce the Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey are limited to a slight change in formulation. The proposed Medihoney Hydrogel Sheet Dressings with Leptospermum Honey are hydrogel dressings containing 63% Manuka Honey compared to the parent Medihoney Primary Dressings which are comprised of 80% Manuka Honey and 20% sodium alginate powder and the L-Mesitran® Dressings which are hydrogel dressings containing ~30% honey. This slight change in formulation provides the user with a wider variety of honey dressings and does not represent a significant change in technological characteristics.

The intended use of the Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey and the predicate devices are identical in that they are all intended to provide a moist environment conducive to wound healing. The Derma Sciences Medihoney Hydrogel Sheet Dressings with Leptospermum Honey are identical to the parent Medihoney Dressings and the L-Mesitran® Dressings in indications in that they are all indicated for management of wounds including partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

8. Summary of Non-clinical Performance Testing As Basis for Substantial Equivalence

Biocompatibility testing performed to support the formulation change for the modified dressings demonstrates that the Medihoney Hydrogel Sheet Dressings with Leptospermum Honey are safe for their intended use. The biocompatibility testing included cytotoxicity, systemic toxicity, sensitization, and irritation testing (acute irritation in rabbit testing).

9. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was conducted or required in support of this premarket clearance notification.

10. Summary of other Information

This submission included comparison of intended use statements, proposed product labeling and summary information and labeling on predicate devices.

11. Conclusions Drawn From Non-clinical and Clinical Tests

Based on the information provided in this 510(k), Derma Sciences believes that the proposed Medihoney Hydrogel Sheet Dressings with Leptospermum Honey is

substantially equivalent to the previously cleared parent Medihoney Primary Wound Dressings with Manuka Honey, and the L-Mesitran® Dressing Family. The proposed device raises no new issues of safety and effectiveness. The non-clinical testing performed demonstrates that the proposed device met all test specifications and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Derma Sciences, Inc.
% Medical Device Consultants, Inc.
Mr. Ronald S. Warren
11440 W. Bernardo Court, Suite 300
San Diego, California 92127

JUL 27 2011

Re: K110546
Trade/Device Name: Derma Sciences Medihoney Hydrogel Sheet Dressings (Adhesive and Non-adhesive) with Leptospermum Honey
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 9, 2011
Received: June 10, 2011

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110546

Device Name: Derma Sciences Medihoney Hydrogel Sheet Dressings (Adhesive and Non-adhesive) with Leptospermum Honey

Indications for Use:

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- minor abrasions
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- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110546